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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,674	02/14/2002	Kenneth K. Sokoll	1151-4172	1691
27123	7590	10/12/2004	EXAMINER	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,674

Applicant(s)

SOKOLL, KENNETH K.

Examiner

Jane Zara

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1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to an immunostimulatory complex, classified in classes 530 and 536, subclasses 300 and 23.1, respectively.
- II. Claims 24-63, drawn to a process of preparing a stabilized immunostimulatory complex, classified in class 424, subclass 1.29.
- III. Claims 64-69, drawn to a pharmaceutical composition comprising an immunostimulatory complex and a biodegradable polymer, classified in class 514, subclass 44.
- IV. Claims 70-75, drawn to a method of producing an immune response in a host, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise methods that are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of the different Groups comprise steps which are not required for or present in the methods of the other groups, as well as requiring different reactive conditions and different biological systems for each of the distinct methods

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claimed: the method of preparing a stabilized immunostimulatory complex requires different and distinct steps from producing an immune response in a host: mixing different biological components in a composition (Group II) and administration of a composition to a subject to elicit a biological response (Group IV). The end result of the methods are different: stabilizing an immunostimulatory complex in a composition using various chemical and biological components (Group II); producing an immune response in a subject (Group IV). Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products are chemically, biologically, structurally and functionally distinct from each other and thus one does not render the other obvious. The products of Group I comprise CpG oligonucleotides and peptide immunogens with net charges that depend on the sequences of each of the constituents; Group III comprises CpG oligonucleotides, peptide immunogens and biocompatible polymers or emulsions for in vivo administration. The compositions of Group III are independent and distinct from the compositions of Group I: they differ in the chemical compositions, chemical properties, and comprise different biological properties (e.g. the compositions of Group III would have different stabilizing characteristics in vivo than the products of Group I). A search of the products of Group I would not be coextensive with the search required for proper examination of Group III.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of making the immunostimulatory complex can be used to make other complexes comprising materially different components (e.g. with structurally and chemically different compositions).

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of producing an immune response in a host can be practiced with other materially different products (e.g. with immunostimulatory complexes comprising other products, including different oligonucleotide sequences or peptides).

The examiner has required restriction between product and process claims of Groups I through IV. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or**

allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Group I is further restricted as follows: Applicant is required to elect one peptide immunogen or sequence from claims 3, 16, 17 and 19-23. Applicant is further required to elect one oligonucleotide sequence from claims 12-14. Pursuant to 35 U.S.C. 121

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and 37 C.F.R. 1.141, these different peptides and oligonucleotides are subject to restriction. Each of these peptides and oligonucleotides is considered to be structurally independent, because each is represented by a unique nucleotide or amino acid sequence. Furthermore, a search of all the sequences and peptides claimed presents an undue burden on the Patent and Trademark Office to search and examine.

Groups II-IV are further restricted as follows: Applicant is required to elect one biocompatible emulsive or polymer from claims 42-45, 54, 56, 57, 66-69. Applicant is further required to elect one oil phase further adjuvant from claims 50, 51; one aqueous phase further adjuvant from claims 52 and 53; or one soluble further adjuvant from claims 62 and 63 as appropriate. The different compounds are chemically and structurally distinct due to their diverse chemical structures and expected different chemical properties and reactive conditions. These chemically diverse compounds impose a serious burden on the examiner to perform a complete search of the corresponding defined areas of the patent and non-patent literature. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the proper examination of this application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ
10-1-04

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